K112742

Aalto Scientific, Ltd.

510(k) Notification
Audit® MicroLQ™ Spinal Fluid

JUN 15 2012

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
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Carlsbad, CA 92008
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B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
Telephone: (760) 431-7922 Ext. 118
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C. Date of Summary Preparation

June 13, 2012

D. Device Identification

Product Trade Name:	Audit® MicroLQ™ Spinal Fluid
Common Name:	Spinal Fluid
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

Device to Which Substantial Equivalence is Claimed:

Product Trade Name:	Audit® MicroCV™ Protein Linearity Set Aalto Scientific, Ltd., Carlsbad, CA K101216

E. Description of the Device

The Audit® MicroLQ™ Spinal Fluid is a human based, liquid set of QC material. Each level of the set contains Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydogenase (LD), Microalbumin, Microprotein, and Sodium analytes. It is used to confirm the proper calibration of Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydogenase (LD), Microalbumin, Microprotein, and Sodium

F. Statement of Intended Use

Audit® Micro*LQ*™ Spinal Fluid Control is a quality control material intended for monitoring the

precision of laboratory testing procedures.
When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides.
The Audit® MicroLQ™ Spinal Fluid is for In Vitro Diagnostic use only.

G. Summary of Performance Data

Stability studies have been performed to determine the shelf life for the Audit® MicroLQ™ Spinal Fluid Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Shelf Life: Two years, when stored unopened at 2 - 8° C.

Open Vial: 30 days, when stored at 2 - 8° C.

Note: Real time studies are ongoing to support the shelf life of this product.

Auto Scientific, Ltd.

510(k) Notification
Audit® MicroLQ™ Spinal Fluid

H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit® MicroLQ™ Spinal Fluid Set (New Device)	Audit™ MicroCV™ Protein Linearity Set (K101216)
Intended Use	Audit® Micro*LQ*™ Spinal Fluid Control is a quality control material intended for monitoring the precision of laboratory testing procedures. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroLQ™ Spinal Fluid is for In Vitro Diagnostic use only.	Same
Number of Analytes per vial	10	7
Contents	6 x 3 mL	5 x 5 mL
Matrix	Human Based Serum	Same
Type of Analytes	Chloride, Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Lactate, Lactate Dehydogenase (LD), Microalbumin, Microprotein, and Sodium	Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin
Form	Liquid	Same
Storage	2 to 8° C Until expiration date	Same
Open Bottle Stability	30 days at 2 to 8° C	24 hours at 2 to 8°

I. Conclusions

Based upon the purpose of the device and the descriptions of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Aalto Scientific, Ltd.
c/o Dessi Lyakov
1959 Kellogg Avenue
Carlsbad, CA 92008

JUN 15 2012

Re: k112742
Trade Name: Audit® MicroLQ™ Spinal Fluid Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: April 23, 2012
Received: April 25, 2012

Dear Dessi Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K112742

Device Name: AUDIT® MicroLQ™ Spinal Fluid Control Set

Indications For Use:

Audit® Micro*LQ*™ Spinal Fluid Control is a quality control material intended for monitoring the precision of laboratory testing procedures.
When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides.
The Audit® MicroLQ™ Spinal Fluid is for In Vitro Diagnostic use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off Office of In Vitro
Diagnostic Device Evaluation and Safety

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